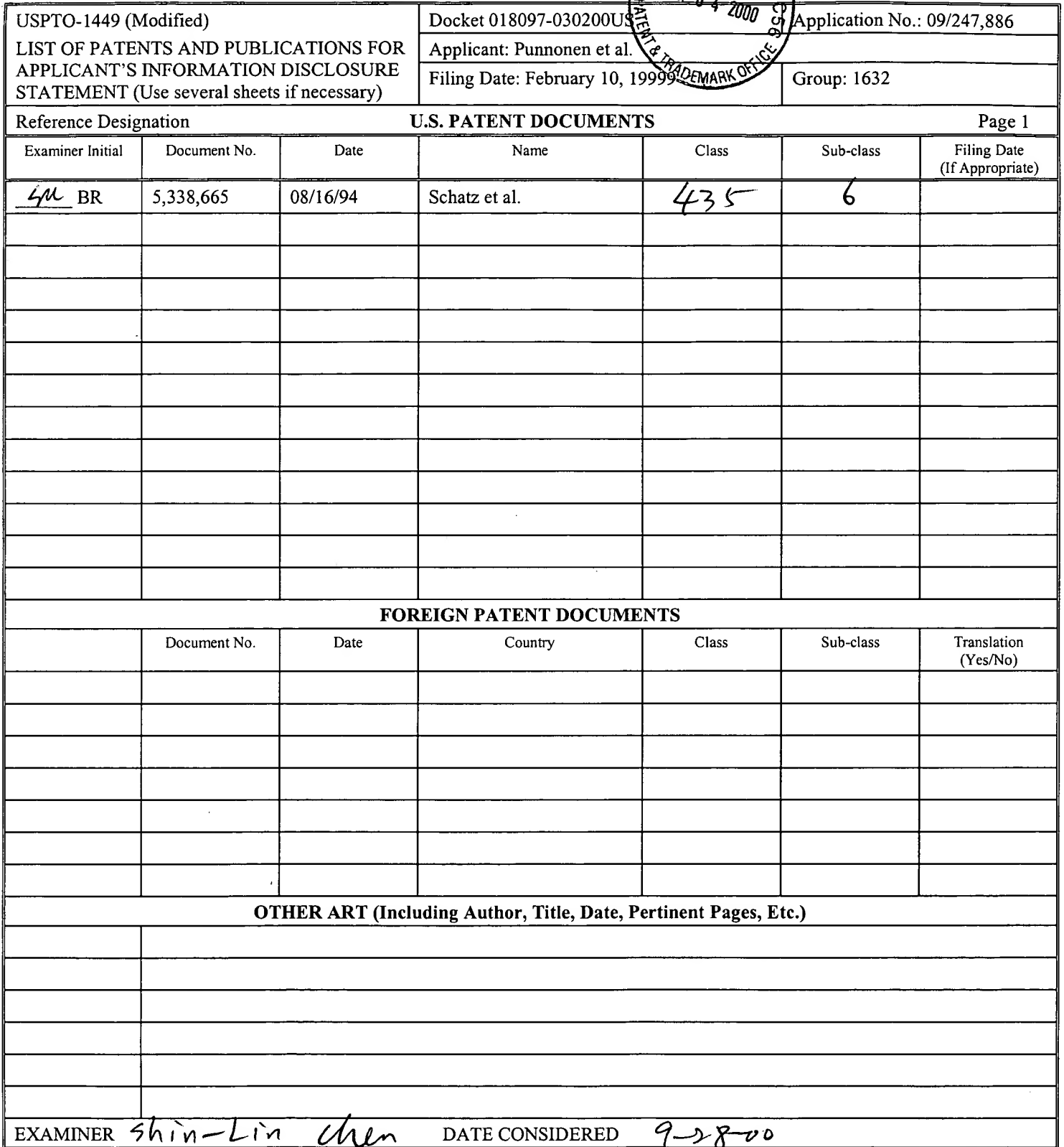


| FORM PTO-1449 (Modified) | | | Attorney Docket No.: 18097-030200US | | Application No.: 09/247,886 | |
|---|---|------------|-------------------------------------|-------|-----------------------------|------------------------------|
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | | Applicant: Punnonen et al. | | | |
| | | | Filing Date: February 10, 1999 | | Group: 1632 | |
| Reference Designation | | | U.S. PATENT DOCUMENTS | | | Page 1 |
| Examiner Initial | Document No. | Date | Name | Class | Sub-class | Filing Date (If Appropriate) |
| <u>SM</u> AA | 5,939,250 | 08/17/99 | Short | 435 | 4 | — |
| <u>SM</u> AB | 5,605,793 | 2/25/97 | Stemmer, et al. | 435 | 6 | — |
| <u>SM</u> AC | 5,834,252 | 11/10/98 | Stemmer, et al. | 435 | 91.1 | — |
| <u>SM</u> AD | 5,830,721 | 11/03/98 | Stemmer, et al. | 435 | 172.1 | — |
| <u>SM</u> AE | 5,811,238 | 09/22/98 | Stemmer, et al. | 435 | 6 | — |
| <u>SM</u> AF | 5,928,905 | 07/27/99 | Stemmer, et al. | 435 | 91.1 | — |
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| <u>SM</u> AG | WO 97/20078 | 5 June 97 | PCT | — | — | — |
| <u>SM</u> AH | WO 94/25608 | 10 Nov. 94 | PCT | — | — | — |
| <u>SM</u> AI | WO 97/35957 | 2 Oct. 97 | PCT | — | — | — |
| <u>SM</u> AJ | WO 96/23882 | 8 Aug. 96 | PCT | — | — | — |
| <u>SM</u> AK | WO 95/26718 | 12 Oct. 95 | PCT | — | — | — |
| <u>SM</u> AL | WO98/27230 | 25 June 98 | PCT | — | — | — |
| <u>SM</u> AM | WO 95/22625 | 24 Aug. 95 | PCT | — | — | — |
| <u>SM</u> AN | WO 96/33207 | 24 Oct. 96 | PCT | — | — | — |
| <u>SM</u> AO | WO 98/13487 | 2 April 98 | PCT | — | — | — |
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| <u>SM</u> AP | Attridge et al., "Oral delivery of foreign antigens by attenuated Salmonella: consequences of prior exposure to the vector strain," <i>Vaccine</i> 15(2): 155-162 (1997). | | | | | |
| <u>SM</u> AQ | Choate and Khavari, "Sustainability of Keratinocyte Gene Transfer and Cell Survival in vivo," <i>Human Gene Ther.</i> 8: 895-901 (1997). | | | | | |
| <u>SM</u> AR | Christians, F.C. et al., "Directed evolution of thymidine kinase for AZT phosphorylation using DNA family shuffling," <i>Nature Biotechnology</i> 17:259-264 (1999) | | | | | |
| <u>SM</u> AS | Courvalin, et al., "Gene transfer from bacteria to mammalian cells," <i>C.R. Acad. Sci. III</i> 18: 1207-12 (1995). | | | | | |
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| <u>SM</u> AU | Cramer, A. et al., "Construction and evolution of antibody-phage libraries by DNA shuffling," <i>Nature Medicine</i> 2:100-103 (1996) | | | | | |
| <u>SM</u> AV | Cramer, A. et al., "DNA Shuffling of a family of genes from diverse species accelerates directed evolution," <i>Nature</i> 391:288-291 (1998) | | | | | |
| <u>SM</u> AW | Cramer, A. et al., "Improved Green Fluorescent Protein by Molecular Evolution Using DNA Shuffling," <i>Nature Biotechnology</i> 14:315-319 (1996) | | | | | |
| <u>SM</u> AX | Cramer, A. et al., "Molecular evolution of an arsenate detoxification pathway by DNA shuffling," <i>Nature Biotechnology</i> 15:436-438 (1997) | | | | | |
| <u>SM</u> AY | Deng, H., et al., "Sustainable cutaneous gene delivery," <i>Nature Biotechnol.</i> 15: 1388-1391 (1997). | | | | | |
| <u>SM</u> AZ | Fox, M.E., et al. "Anaerobic bacteria as a delivery system for cancer gene therapy: in vitro activation of 5-fluorocytosine by genetically engineered clostridia," <i>Gene Ther.</i> 3: 173-178 (1996). | | | | | |
| <u>SM</u> BA | Fritz, J.D., "Gene Transfer into Mammalian Cells Using Histone-Condensed Plasmid DNA," <i>Human Gene Therapy</i> 7: 1395-1404 (1996). | | | | | |

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| FORM PTO-1449 (Modified) | | Attorney Docket No.: 18097-030200US | Application No.: 09/247,886 |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | Applicant: Punnonen et al. | |
| | | Filing Date: February 10, 1999 | Group: 1632 |
| <u>Gu</u> BB | Gates, C.M. <i>et al.</i> , "Affinity Selective Isolation of Ligands from Peptide Libraries Through Display on a <i>lac</i> Repressor 'Headpiece Dimer'" <i>J. Mol. Biol.</i> 255 :1-14 (1995) | | |
| <u>Gu</u> BC | Hilgers, A.R., et al., "Caco-2 Cell Monolayers as a Model for Drug Transport Across the Intestinal Mucosa," <i>Pharmaceutical Res.</i> 7 (9): 902-910 (1990). | | |
| <u>Gu</u> BD | Khavari and Krueger, "Cutaneous Gene Therapy," <i>Adv. Clin. Res., Dermatologic Clinics</i> , 15 (1): 27-35 (1997). | | |
| <u>Gu</u> BE | Minshull, J. and Willem P.C. Stemmer, "Protein evolution by molecular breeding," <i>Current Opinion in Chemical Biology</i> 3 :284-290 (1999) | | |
| <u>Gu</u> BF | Oggoni, M.R. and Pozzi, G., "A host-vector system for heterologous gene expression in <i>Streptococcus gordonii</i> ," <i>Gene</i> 169 :85-90 (1996). | | |
| <u>Gu</u> BG | Patten, P.A., et al., "Applications of DNA Shuffling to Pharmaceuticals and Vaccines," <i>Current Op. in Biotech.</i> 8 : 724-733 (1997). | | |
| <u>Gu</u> BH | Pisetsky, D.S., "Immune Activation by Bacterial DNA: A New Genetic Code," <i>Immunity</i> 5 : 303-310 (1996). | | |
| <u>Gu</u> BI | Sizemore, et al., "Attenuated <i>Shigella</i> as a DNA Delivery Vehicle for DNA-Mediated Immunization," <i>Science</i> 270 :299-302 (1995) | | |
| <u>Gu</u> BJ | Stemmer, W.P.C. and N.W. Soong, "Molecular breeding of viruses for targeting and other clinical properties," <i>Tumor Targeting</i> 4 :1-4 (1999) | | |
| <u>Gu</u> BK | Stemmer, W.P.C. <i>et al.</i> , "Single-step assembly of a gene and entire plasmid from large numbers of oligodeoxyribonucleotides," <i>Gene</i> 164 :49-53 (1995) | | |
| <u>Gu</u> BL | Stemmer, W.P.C., "DNA shuffling by random fragmentation and reassembly: <i>In vitro</i> recombination for molecular evolution," <i>Proc. Natl. Acad. Sci. USA</i> 91 :10747-10751 (1994) | | |
| <u>Gu</u> BM | Stemmer, W.P.C., "Rapid evolution of a protein <i>in vitro</i> by DNA shuffling," <i>Nature</i> 370 :389-391 (1994) | | |
| <u>Gu</u> BN | Stemmer, W.P.C., "Searching Sequence Space," <i>Biotechnology</i> 13 :549-553 (1995) | | |
| <u>Gu</u> BO | Stemmer, W.P.C., "Sexual PCR and Assembly PCR," <i>The Encyclopedia of Molecular Biology</i> , VCH Publishers, New York pp. 447-457 (1996) | | |
| <u>Gu</u> BP | Stemmer, W.P.C., "The Evolution of Molecular Computation," <i>Science</i> 270 :1510 (1995) | | |
| <u>Gu</u> BQ | Zhang, J. <i>et al.</i> , "Directed evolution of a fucosidase from a galactosidase by DNA shuffling and screening," <i>Proc. Natl. Acad. Sci. USA</i> 94 :4504-4509 (1997) | | |
| EXAMINER <u>Shin-Lin Chen</u> DATE CONSIDERED <u>9-28-00</u> | | | |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.





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FORM PTO-1449 (Modified) **SEP 6 5 2000**
 LIST OF PATENTS AND PUBLICATIONS FOR
 APPLICANT'S INFORMATION DISCLOSURE
 STATEMENT (Use several sheets if necessary)

Attorney Docket No.: 18097-030200US
 Applicant: Juha Punnonen et al.
 Filing Date: February 10, 1999

Application No.: 09/247,886
 Group: 1633

| Reference Designation | | | U.S. PATENT DOCUMENTS | | | Page 1 |
|--------------------------|--------------|----------|-----------------------------|-------|-----------|---------------------------------|
| Examiner Initial | Document No. | Date | Name | Class | Sub-class | Filing Date (If Appropriate) |
| <u>SL</u> AA | 5,264,563 | 11/23/93 | Huse | 536 | 25.3 | |
| <u>SL</u> AB | 5,470,725 | 11/28/95 | Borriss, <i>et. al.</i> | 435 | 93 | |
| <u>SL</u> AC | 5,523,388 | 06/04/96 | Huse | 536 | 22.1 | |
| <u>SL</u> AD | 5,589,466 | 12/31/96 | Felgner, <i>et. al.</i> | 514 | 44 | |
| <u>SL</u> AE | 5,593,972 | 01/14/97 | Weiner, <i>et. al.</i> | 514 | 44 | |
| <u>SL</u> AF | 5,698,426 | 12/16/97 | Huse | 435 | 172.3 | |
| <u>SL</u> AG | 5,703,057 | 12/30/97 | Johnston, <i>et. al.</i> | 514 | 44 | |
| <u>SL</u> AH | 5,723,323 | 03/03/98 | Kauffman, <i>et. al.</i> | 435 | 172.3 | |
| <u>SL</u> AI | 5,763,192 | 06/09/98 | Kauffman, <i>et. al.</i> | 435 | 7.1 | |
| <u>SL</u> AJ | 5,770,434 | 06/23/98 | Huse | 435 | 252.33 | |
| <u>SL</u> AK | 5,783,386 | 07/21/98 | Jacobs, Jr., <i>et. al.</i> | 435 | 6 | |
| <u>SL</u> AL | 5,808,022 | 09/15/98 | Huse | 536 | 22.1 | |
| <u>SL</u> AM | 5,814,476 | 09/29/98 | Kauffman, <i>et. al.</i> | 435 | 69.1 | |
| <u>SL</u> AN | 5,817,483 | 10/06/98 | Kauffman, <i>et. al.</i> | 435 | 69.1 | |
| <u>SL</u> AO | 5,824,469 | 10/20/98 | Horwitz, <i>et. al.</i> | 435 | 6 | |
| <u>SL</u> AP | 5,824,514 | 10/20/98 | Kauffman, <i>et. al.</i> | 435 | 91.1 | |
| <u>SL</u> AQ | 5,830,696 | 11/03/98 | Short | 435 | 69.1 | |
| <u>SL</u> AR | 5,837,458 | 11/17/98 | Minshull, <i>et. al.</i> | 435 | 6 | |
| <u>SL</u> AS | 5,866,363 | 02/02/99 | Pieczenik | 435 | 69.1 | |
| <u>SL</u> AT | 5,871,974 | 02/16/99 | Huse | 435 | 69.7 | |
| <u>SL</u> AU | 5,955,358 | 09/21/99 | Huse | 435 | 328 | |
| <u>SL</u> AV | 5,958,672 | 09/28/99 | Short | 435 | 4 | |
| <u>SL</u> AW | 5,965,408 | 10/12/99 | Short | 435 | 91.1 | |
| <u>SL</u> AX | 5,976,862 | 11/02/99 | Kauffman, <i>et. al.</i> | 435 | 252.3 | |
| <u>SL</u> AY | 5,989,553 | 11/23/99 | Johnston, <i>et. al.</i> | 424 | 190.1 | |
| <u>SL</u> AZ | 6,001,574 | 12/14/99 | Short, <i>et. al.</i> | 435 | 6 | |
| <u>SL</u> BA | 6,004,788 | 12/21/99 | Short | 435 | 183 | |
| <u>SL</u> BB | 6,030,779 | 02/29/00 | Short | 435 | 6 | |
| <u>SL</u> BC | 6,054,267 | 04/25/00 | Short | 435 | 6 | |
| <u>SL</u> BD | 6,057,103 | 05/02/00 | Short | 435 | 6 | |
| <u>SL</u> BE | 6,096,548 | 08/01/00 | Stemmer | 435 | 440 | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
| | Document No. | Date | Country | Class | Sub-class | Translation (Yes/No) |
| <u>SL</u> BF | 0 544 809 B1 | 06/09/93 | Europe | | | |
| <u>SL</u> BG | 0 563 296 B1 | 10/06/93 | Europe | | | |

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FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)

Attorney Docket No.: 18097-030200US

Applicant: Juha Punnonen et al.

Filing Date: February 10, 1999

Application No.: 09/247,888

Group: 1633

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|---|--|----------|-----|------|-------|----|
| <u>6u</u> BH | WO 90/14424 | 11/29/0 | PCT | C12N | 15/00 | |
| <u>6u</u> BI | WO 92/06176 | 04/16/92 | PCT | C12N | 15/00 | No |
| <u>6u</u> BJ | WO 94/06911 | 03/31/94 | PCT | C12N | 15/31 | No |
| <u>6u</u> BK | WO 94/11496 | 05/26/94 | PCT | C12N | 15/00 | No |
| <u>6u</u> BL | WO 96/31613 | 10/10/96 | PCT | C12N | 15/87 | No |
| <u>6u</u> BM | WO 97/35966 | 10/02/97 | PCT | C12N | 15/00 | No |
| <u>6u</u> BN | WO 98/13485 | 04/02/98 | PCT | C12N | 15/00 | No |
| <u>6u</u> BO | WO 98/31816 | 07/23/98 | PCT | C12N | 15/55 | No |
| <u>6u</u> BP | WO 98/31837 | 07/23/98 | PCT | C12Q | 1/68 | No |
| OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | |
| <u>6u</u> BQ | Affholter, J. and Stemmer WPC, "Directed evolution of proteins and pathways by DNA shuffling", <i>Book of Abstracts</i> , 216th ACS National Meeting, Boston, August 23-27, BIOT-042 | | | | | |
| <u>6u</u> BR | Barry, et al., "Production of Monoclonal Antibodies by Genetics Immunization," <i>Short Technical Reports, in Biotechniques</i> , 16 (4):616 (1994) | | | | | |
| <u>6u</u> BS | Barry, et al., "Protection against mycoplasma infection using expression-library immunization," <i>Nature</i> 377:632 (10/19/95) | | | | | |
| <u>6u</u> BT | Beattie, et al., "Cloning and characterization of T-cell reactive protein antigens from <i>Listeria monocytogenes</i> ," <i>Infection and Immunity</i> 58 (9):2792-2803 (Sept. 1990) | | | | | |
| <u>6u</u> BU | Conroy, et al., "Immune response to a carcinoembryonic antigen polynucleotide vaccine," <i>Cancer Research</i> 54: 1164-1168 (March 1, 1994) | | | | | |
| <u>6u</u> BV | Coppel et al., "Identification of a cDNA clone encoding a mature blood stage antigen of <i>Plasmodium falciparum</i> by immunization of mice with bacterial lysates," <i>EMBO J.</i> 3(2): 403-407 (1984). | | | | | |
| <u>6u</u> BW | Hedstrom, et al., "Prospects and strategies for development of DNA vaccines against malaria," <i>59th Forum in Immunology</i> pp 476-482 | | | | | |
| <u>6u</u> BX | Howard, Abstract No. 528494, "Chemistry of the future: Exploitation of the power of biology," Abstracts of Papers of the <i>Amer. Chem. Soc.</i> , V216, 3 (Aug. 23, 1998). | | | | | |
| <u>6u</u> BY | Khusmith, et al., "Protection Against Malaria by Vaccination with Sporozoite Surface Protein 2 Plus CS Protein," <i>Science</i> 252: Reports, 715-718 (1991). | | | | | |
| <u>6u</u> BZ | MacKay et al., "Production of immunologically active surface antigens of hepatitis B virus by <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 78(7): 4510-4514 (1981). | | | | | |
| <u>6u</u> CA | Pascopella et al., "Identification of a Genomic Fragment of <i>Mycobacterium tuberculosis</i> Responsible for In Vivo Growth Advantage," <i>Inf. Agents and Dis.</i> 2: 282-284 (1994). | | | | | |
| <u>6u</u> CB | Pascopella et al., "Use of In Vivo Complementation in <i>Mycobacterium tuberculosis</i> to Identify a Genomic Fragment Associated with Virulence," <i>Inf. and Imm.</i> 62(4): 1313-1319 (1994). | | | | | |
| <u>6u</u> CC | Punnonen, "Evolution of DNA vaccine vectors by gene shuffling," The First Gordon Research Conference on Genetic Vaccines/DNA Vaccines, Plymouth State College, Plymouth, N.H. (1997) (one page). | | | | | |
| <u>6u</u> CD | Punnonen et al., "Evolution of Genetic Vaccines by DNA shuffling," Keystone Symposia on Molecular and Cellular Biology, Molecular Aspects of Viral Immunity, Tamaron, Colorado (1998) (one page). | | | | | |
| <u>6u</u> CE | Stemmer, "DNA sequence evolution by sexual PCR," <i>Experientia</i> (Basel, Switzerland), S09-04, 52(abstract): A25, 28th Annual Meeting of the Swiss Societies for Exp. Biology (1996). | | | | | |
| <u>6u</u> CF | Stemmer, "Directed evolution of proteins, pathways, episomes and viruses by DNA shuffling," <i>FASEB J.</i> 12(8): A1303, Meeting of the Amer. Soc. for Biochem. and Mol. Biol., Washington, D.C. (1998). | | | | | |
| <u>6u</u> CG | Stemmer et al., "Molecular evolution of genes and pathways by DNA shuffling," <i>FASEB J.</i> 11(9): A1124, Annual Meeting of the American Society for Biochemistry and Molecular Biology, San Francisco, California (1997). | | | | | |

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| FORM PTO-1449 (Modified) | | SEP 0 5 2000 | Attorney Docket No.: 18097-030200US | Application No.: 09/247,886 |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | | Applicant: Juha Punnonen et al. | |
| | | | Filing Date: February 10, 1999 | Group: 1633 |
| <u>4u</u> CH | Tang et al., "Genetic immunization is a simple method for eliciting an immune response," <i>Nature</i> 356: 152-155 (1992). | | | |
| <u>4u</u> CI | Ugen et al., "DNA Inoculation as a Novel Vaccination Method against Human Retroviruses with Rheumatic Disease Associations," <i>Immunol. Res.</i> 13:154-162 (1994). | | | |
| <u>4u</u> CJ | Ulmer and Liu, "ELI's coming: expression library immunization and vaccine antigen discovery," <i>Trends in Microbiology</i> 170: 4(5) : 170-171 (1996). | | | |
| <u>4u</u> CK | Ulmer et al., "Heterologous Protection Against Influenza by DNA Encoding a Viral Protein," <i>Science</i> 259: 1745-1749 (1993). | | | |
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| <u>4u</u> CM | Wang, et al., "Gene inoculation generates immune responses against human immunodeficiency virus type 1," <i>Proc. Natl. Acad. Sci. USA</i> 90:4156-4160 (1993) | | | |
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| <u>4u</u> CO | Williams et al., "Immunotherapeutic Strategies Targeting Rheumatoid Synovial T-Cell Receptors by DNA Inoculation," <i>Immunol. Res.</i> 13: 145-153 (1994). | | | |
| <u>4u</u> CP | Xiang and Ertl, "A simple method to test the ability of individual viral proteins to induce immune responses," <i>J. of Virological Methods</i> 47: 103-116 (1994). | | | |
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| CR | | | | |
| CS | | | | |
| CT | | | | |
| EXAMINER <u>Shin-Lin Chen</u> DATE CONSIDERED <u>10-11-00</u> | | | | |

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